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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,279	12/26/2006	Keiko Takahashi	1056-0133PUS1	6051

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EXAMINER

LOEWE, SUN JAE Y

ART UNIT	PAPER NUMBER
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1626

NOTIFICATION DATE	DELIVERY MODE
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03/26/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/571,279	Applicant(s) TAKAHASHI ET AL.	
	Examiner SUN JAE Y. LOEWE	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 7-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1-3-2008; 3-9-2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-22 are pending in the instant application.

Election/Restrictions

2. Applicant's election with traverse of Group I in the reply filed on February 15, 2008 is acknowledged. The traversal is on the ground(s):

~~Accordingly, Applicants are not claiming what was disclosed in the prior art. Thus, the Examiner's reasoning for the restriction is factually incorrect and the resulting determination of lack of unity of invention is without basis and must be withdrawn.~~

Applicant's argument has been considered, however, it is not found persuasive for the following reason. The claims are directed to more than one crystalline form of a compound. Thus, the special technical feature linking the inventions is the compound itself which, as stated in the instant specification, is taught in the art.

The restriction requirement is still deemed proper and is hereby made FINAL.

3. Claims 7-22 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter. Applicant timely traversed the restriction requirement in the response dated February 15, 2008.

Priority

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

5. The information disclosure statements (dated March 9, 2006 and January 3, 2008) were filed in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. The statements were considered. Signed copies of form 1449 enclosed herewith.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1 and 2 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The prior art provides a method of comparing X-ray powder diffraction data by overlaying and aligning the respective films or plots. The comparison of peak positions and intensities shows whether the crystalline forms are the same or different (Byrn et al., page 63). An X-ray diffraction pattern is a fingerprint that uniquely defines a specific crystalline form; the presence and absence of peaks are both important factors in establishing this fingerprint.

The claims are drawn to a crystalline form of ~~N-(3-cyano-4-methyl-1H-indol-7-yl)-3-cyanobenzenesulfonamide~~ identified by the x-ray diffraction (XRD) pattern of Figure 1. However, the claims recite merely one or two of the peaks in the XRD pattern. The specification does not

provide guidance or reasoning as to why an “abbreviated pattern” is sufficient to uniquely identify the claimed crystalline form.

Therefore, the claims are drawn to subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

7. The specification is enabling for the preparation of N-(3-cyano-4-methyl-1*H*-indol-7-yl)-3-cyanobenzenesulfonamide identified by the full x-ray diffraction pattern shown in Figure 1 (alone, or in combination with other physical properties/data). The specification is not enabling for the preparation of other crystalline forms of N-(3-cyano-4-methyl-1*H*-indol-7-yl)-3-cyanobenzenesulfonamide (see below, “The breadth of the claims” and “The nature of the invention”). Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with the claims.

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8USPQ2s 1400, 1404 (Fed. Cir. 1988). MPEP 2164.01(a) states “There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue”. The factors are applied below to the instant claims.

The breadth of the claims

The claims encompass crystalline N-(3-cyano-4-methyl-1*H*-indol-7-yl)-3-cyanobenzenesulfonamide characterized by:

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- a) one or two x-ray diffraction peaks or
- b) one or two IR band or
- c) one or two NMR peaks.

The nature of the invention

Brittain (p. 228-229) states that methodologies, other than structural determinations, that are used to characterize polymorphs "must be considered as sources of supporting and ancillary information; they cannot be taken as definitive proof for the existence of polymorphism by themselves".

In view of the above, the claims as drafted are not drawn to a unique crystalline form. Thus, within the broadest reasonable interpretation, the claims encompass more than one polymorphic form of N-(3-cyano-4-methyl-1H-indol-7-yl)-3-cyanobenzenesulfonamide.

The state of the prior art/level of ordinary skill/level of predictability

The state of the art for preparing polymorphs of a given compound is unpredictable (eg. see Chawla et al., p. 9, 1st and 2nd paragraphs):

- The number or existence of solid forms cannot be predicted.
- The more diligently any system is studied the larger the number of polymorphs discovered
- It is not commonly known in the art, or predictable, how different solid forms are made (Newman et al., p. 898, 2nd column, last paragraph).

The amount of direction provided by the inventor/existence of working examples

Direction/working examples limited to the preparation of a crystalline form of N-(3-cyano-4-methyl-1H-indol-7-yl)-3-cyanobenzenesulfonamide with x-ray diffraction pattern in Figure 1.

The quantity of experimentation needed to make or use the invention

MPEP 2164.01(a) states:

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Based on the evidence regarding each of the above factors (see discussion above), the specification, at the time the application was filed, would not have taught one of ordinary skill in the art how to practice the claimed invention without undue experimentation.

The instant claims *prima facie* lack enablement.

Claim Rejections - 35 USC § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-6 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the term "Form C" is not defined in the instant claim; thus, one must refer back to the disclosure for the definition. A claim referring to the specification is improper

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except in rare instances and fails to particularly point out the subject matter that applicant regards as the invention. Ex parte Fressola, 27 USPQ 2d 1608 (1993).

Conclusion

9. No claims allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUN JAE Y. LOEWE whose telephone number is (571)272-9074. The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SL
3-18-2008

/Kamal Saeed, Ph.D./
Primary Examiner
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